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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
FORMAN, BETTY J	

ART UNIT	PAPER NUMBER
1655	

DATE MAILED: 01/02/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/451,666	Applicant(s) ITO ET AL.	
	Examiner BJ Forman	Art Unit 1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 October 2001* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *6,7,9-12,21 and 23-36* is/are pending in the application.

4a) Of the above claim(s) *9-12* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *6,7,21 and 23-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. This action is in response to papers filed 19 October 2001 in Paper No. 24 in which claims 6, 7, 21 and 23 were amended, claims 4, 5, 8 and 22 were canceled and claims 24-36 were added. All of the amendments have been thoroughly reviewed and entered. The previous rejections in the Office Action of Paper No. 21 dated 25 May 2001 are withdrawn in view of the amendments. All of the arguments have been thoroughly reviewed and are discussed below. New grounds for rejection are discussed.

Currently claims 6, 7, 21 and 23-36 are under prosecution.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

3. Claims 7 and 24 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Beattie (U.S. Patent No. 5,843,767, issued 1 December 1998).

Regarding Claim 7, Beattie et al. disclose the method of Claim 24 wherein the binding agent is silylation-coating (Column 13, lines 55-64).

Regarding Claim 24, Beattie et al. disclose a method for producing a biochip comprising: providing a binding agent wherein said binding agent is capable of immobilizing a

probe to the biochip; spotting the binding agent to a plurality of positions on the biochip; and spotting a plurality of probes onto the positions where the binding agent is spotted thereby producing a biochip (Column 13 line 51-Column 14, line 11).

Response to Arguments

4. Applicant argues that Beattie et al. does not teach a method for making biochips comprising spotting a surface with binding agents because the devices of Beattie comprise a multiplicity of discrete and isolated regions into which a binding agent is flowed. The arguments have been considered but are deemed moot in view of the cancelled claims, withdrawn rejections and new grounds for rejection. However, the argument is considered as it applies to the new claims and new grounds for rejection. The argument is not found persuasive because the claims are very broadly drawn to a method for producing a biochip comprising "spotting" a binding agent. The claims are given the broadest reasonable interpretation consistent with the broad claim language wherein "spotting" methods are not defined. Webster's Ninth New Collegiate Dictionary (Merriam Webster, Inc. 1991, page 1141) defines "spotting" as to mark in a spot; to locate or identify a spot; to lie at intervals in or over; to place at intervals or in a desired spot all of which encompass the method step of Beattie et al. wherein they place the binding agent at intervals; locate a spot for binding agent or mark the binding agent in a spot. Given the broadest reasonable interpretation in view of well known definitions taught by Webster's, Beattie et al. disclose spotting the binding agent (Column 13, lines 51-62). Therefore, Beattie et al. disclose the method of making a biochip as claimed.

5. Claims 6, 23, 25, 26, 28 and 29 are rejected under 35 U.S.C. 102(e) as being anticipated by Balch (U.S. Patent No. 6,083,763, filed 31 December 1997).

Regarding Claim 6, Balch discloses the method of Claim 26 wherein the plate comprise a material selected from the group consisting of a nylon membrane, a glass and a polymer plastic (Column 9, lines 56-60)

Regarding Claim 23, Balch discloses the method of Claim 26 wherein the plate is substantially planar (Column 9, lines 56-60).

Regarding Claim 25, Balch discloses a method for producing a biochip comprising: providing a mixture of a binding agent and a probe (i.e. biotin derivatized nucleic acid and the attached probe) wherein said binding agent is capable of immobilizing a probe to the biochip having a streptaviden film; spotting the mixture to a plurality of positions on the biochip; and spotting a plurality of probes onto the positions where the binding agent is spotted thereby producing a biochip (Column 6, lines 1-24 and Column 18, lines 55-66). The claims are broadly drawn to a method for producing a biochip comprising providing a mixture of binding agent and probe. Balch teaches a probe attached to a biotin moiety wherein the biotin functions as a binding agent to immobilize the probe to the biochip. The claims are given the broadest reasonable interpretation consistent with the broad claim language and the specification wherein "binding agent" is not clearly define. Because Balch teaches a probe-binding agent mixture, Balch teaches the biochip as claimed.

Regarding Claim 26, Balch discloses a method for producing a biochip comprising: providing a plate (i.e. solid support); providing a mixture of a binding agent and a probe (i.e. biotin derivatized nucleic acid and the attached probe) wherein said binding agent is capable of immobilizing a probe to the biochip having a streptaviden film; spotting the mixture to a plurality of positions on the biochip; and spotting a plurality of probes onto the positions where the binding agent is spotted thereby producing a biochip (Column 6, lines 1-24 and Column 18, lines 55-66). The claims are broadly drawn to a method for producing a biochip comprising providing a mixture of binding agent and probe. Balch teaches a probe attached to a biotin moiety wherein the biotin functions as a binding agent to immobilize the probe to the biochip. The claims are given the broadest reasonable interpretation consistent with the broad claim language and the specification wherein "binding agent" is not clearly define. Because Balch teaches a probe-binding agent mixture, Balch teaches the biochip as claimed.

Regarding Claim 28, Balch discloses the method wherein the mixture is spotted with a tube (Column 12, lines 12-17).

Regarding Claim 29, Balch discloses the method wherein the tube is capillary tube (Column 12, lines 12-17).

6. Claims 6, 21, 23, 25-27 and 30-36 are rejected under 35 U.S.C. 102(e) as being anticipated by Martinsky (U.S. Patent No. 6,101,946, filed 13 November 1998) as taught by TeleChem International (http://www.arrayit.com//products/solutions/mss/mss.html, copyright 1998,1999).

Regarding Claim 6, Martinsky discloses the method of Claim 26 wherein the plate comprises glass i.e. microscope slide (Column 8, lines 53-55).

Regarding Claim 21, Martinsky discloses the method of Claim 27 wherein the pin comprises at least one recessed tip (Column 4, lines 24-34 and Fig. 3 B and 4).

Regarding Claim 23, Martinsky discloses the method of Claim 26 wherein the plate is substantially planar i.e. microscope slide (Column 8, lines 53-55).

Regarding Claim 25, Martinsky discloses a method for producing a biochip comprising: providing a mixture of a binding agent (i.e. Micro-Spotting Solution) and a probe wherein the binding agent is capable of immobilizing the probe to the biochip; and spotting the mixture to a plurality of positions on the biochip wherein the binding agent is only provided on an area of the biochip where the probe is spotted thereby producing a biochip (Column 8, lines 51-58). Additionally, TeleCom International teaches their Micro-Spotting Solution comprises binding agents capable of immobilizing the probe to the biochip (see page 2, Fig. 1).

Regarding Claim 26, Martinsky discloses a method for producing a biochip comprising: providing a plate i.e. slide); providing a mixture of a binding agent (i.e. Micro-Spotting Solution) and a probe wherein the binding agent is capable of immobilizing the probe to the biochip; and spotting the mixture to a plurality of positions on the biochip wherein the binding agent is only

provided on an area of the biochip where the probe is spotted thereby producing a biochip (Column 8, lines 51-58). Additionally, TeleCom International teaches their Micro-Spotting Solution comprises binding agents capable of immobilizing the probe to the biochip (see page 2, Fig. 1).

Regarding Claim 27, Martinsky discloses the method of Claims 25 and 26 wherein the mixture is spotted with a pin (Abstract).

Regarding Claim 30, Martinsky discloses the method of Claim 27 wherein the tip comprises at least one recess (Column 6, lines 21-57).

Regarding Claim 31, Martinsky discloses the method of Claim 30 wherein the recess comprises a concave shape (Column 6, lines 21-57 and Fig. 4).

Regarding Claim 32, Martinsky discloses the method of Claim 31 wherein the recess comprises at least one groove i.e. gap (Column 6, lines 21-57 and Fig. 4).

Regarding Claim 33, Martinsky discloses the method of Claim 32 wherein the groove comprises a radially-shaped groove (Column 6, lines 21-57 and Fig. 4).

Regarding Claim 34, Martinsky discloses the method of Claims 25 and 26 wherein the mixture is suctioned (by immersing the pins in the mixture) and spotted on a plurality of positions on the biochip (Column 7, lines 66-7 and Column 8, lines 13-15).

Regarding Claim 35, Martinsky discloses the method of Claims 25 and 26 wherein the mixture is carried by a tip of a pin and spotted on a plurality of positions on the biochip (Column 8, lines 27-40).

Regarding Claim 36, Martinsky discloses the method of Claims 25 and 26 wherein the mixture is carried by surface tension by a tip of a pin and spotted on a plurality of positions on the biochip i.e. printing results from direct contact with the biochip surface (Column 8, lines 31-33) therefore, the contact breaks the surface tension between the tip and the mixture to provide printing.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Martinsky (U.S. Patent No. 6,101,946, filed 13 November 1998) as taught by TeleChem International (http://www.arrayit.com//products/solutions/mss/mss.html, copyright 1998,1999).

Regarding Claim 7, Martinsky teaches a method for producing a biochip comprising: providing a mixture of a binding agent (i.e. Micro-Spotting Solution) and a probe wherein the binding agent is capable of immobilizing the probe to the biochip; and spotting the mixture to a plurality of positions on the biochip wherein the binding agent is only provided on an area of the biochip where the probe is spotted thereby producing a biochip (Column 8, lines 51-58) and a method for producing a biochip comprising: providing a plate i.e. slide); providing a mixture of a binding agent (i.e. Micro-Spotting Solution) and a probe wherein the binding agent is capable of immobilizing the probe to the biochip; and spotting the mixture to a plurality of positions on the biochip wherein the binding agent is only provided on an area of the biochip where the probe is spotted thereby producing a biochip (Column 8, lines 51-58). Additionally. Martinsky teaches an additional binding agent wherein the binding agent is silyation-coating (Column 8, lines 53-54) but they do not teach their binding agent-probe mixture comprises silyation coating. However, It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the spotting mixture of Martinsky to include the silylated coating to thereby locally spot all binding agents in one step and eliminating the added time and expense of purchasing silylated slides for the obvious benefit of economy of time and labor.

9. Claims 21, 24, 27 and 30-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Martinsky (U.S. Patent No. 6,101,946, filed 13 November 1998) as taught by TeleChem International (http://www.arrayit.com//products/solutions/mss/mss.html, copyright 1998,1999) in view of Beattie (U.S. Patent No. 5,843,767, issued 1 December 1998).

Regarding Claim 21, Martinsky teaches the method wherein the pin comprises at least one recessed tip (Column 4, lines 24-34 and Fig. 3 B and 4).

Regarding Claim 24, Martinsky teaches a method for producing a biochip comprising: providing a binding agent (i.e. Micro-Spotting Solution) wherein the binding agent is capable of immobilizing the probe to the biochip and a probe; spotting the binding agent to a plurality of positions on the biochip and spotting a plurality of probes onto the positions having the binding agent wherein the binding agent is only provided on an area of the biochip where the probe is spotted thereby producing a biochip (Column 8, lines 51-58). Additionally, TeleCom International teaches their Micro-Spotting Solution comprises binding agents capable of immobilizing the probe to the biochip (see page 2, Fig. 1). Martinsky does not teach the binding agent is spotted prior to the step of spotting the probes. However, Beattie et al. teach a similar method wherein a binding agent is spotted onto the biochip prior to spotting the probe wherein their method provides an improved biochip having a high density of probes fixed in isolated a discrete regions (Column 6, lines 7-13 and 21-25). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the spotting steps of Martinsky and to spot a binding agent onto the biochip prior to spotting the probe to thereby provide an high density of probes in discrete and isolated regions for the expected benefit of providing a biochip capable of conducting a multiplicity of individual and simultaneous binding reactions as taught by Beattie et al. (Abstract).

Regarding Claim 27, Martinsky teaches the method wherein the mixture is spotted with a pin (Abstract).

Regarding Claim 30, Martinsky teaches the method wherein the tip comprises at least one recess (Column 6, lines 21-57).

Regarding Claim 31, Martinsky teaches the method wherein the recess comprises a concave shape (Column 6, lines 21-57 and Fig. 4).

Regarding Claim 32, Martinsky teaches the method wherein the recess comprises at least one groove i.e. gap (Column 6, lines 21-57 and Fig. 4).

Regarding Claim 33, Martinsky teaches the method wherein the groove comprises a radially-shaped groove (Column 6, lines 21-57 and Fig. 4).

Regarding Claim 34, Martinsky teaches the method wherein the mixture is suctioned (by immersing the pins in the mixture) and spotted on a plurality of positions on the biochip (Column 7, lines 66-7 and Column 8, lines 13-15).

Regarding Claim 35, Martinsky teaches the method wherein the mixture is carried by a tip of a pin and spotted on a plurality of positions on the biochip (Column 8, lines 27-40).

Regarding Claim 36, Martinsky teaches the method wherein the mixture is carried by surface tension by a tip of a pin and spotted on a plurality of positions on the biochip i.e. printing results from direct contact with the biochip surface (Column 8, lines 31-33) therefore, the contact breaks the surface tension between the tip and the mixture to provide printing.

10. Claims 28 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Martinsky (U.S. Patent No. 6,101,946, filed 13 November 1998) as taught by TeleChem International (http://www.arrayit.com//products/solutions/mss/mss.html, copyright 1998,1999) in view of Beattie (U.S. Patent No. 5,843,767, issued 1 December 1998) as applied

to Claim 24 above and further in view of Balch (U.S. Patent No. 6,083,763, filed 31 December 1997).

Regarding Claims 28 and 29, Martinsky teaches a method for producing a biochip comprising: providing a binding agent (i.e. Micro-Spotting Solution) wherein the binding agent is capable of immobilizing the probe to the biochip and a probe; spotting the binding agent to a plurality of positions on the biochip and spotting a plurality of probes onto the positions having the binding agent wherein the binding agent is only provided on an area of the biochip where the probe is spotted thereby producing a biochip (Column 8, lines 51-58). Additionally, TeleCom International teaches their Micro-Spotting Solution comprises binding agents capable of immobilizing the probe to the biochip (see page 2, Fig. 1). Martinsky does not teach the binding agent is spotted prior to the step of spotting the probes. However, Beattie et al. teach a similar method wherein a binding agent is spotted onto the biochip prior to spotting the probe wherein their method provides an improved biochip having a high density of probes fixed in isolated a discrete regions (Column 6, lines 7-13 and 21-25). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the spotting steps of Martinsky and to spot a binding agent onto the biochip prior to spotting the probe to thereby provide an high density of probes in discrete and isolated regions for the expected benefit of providing a biochip capable of conducting a multiplicity of individual and simultaneous binding reactions as taught by Beattie et al. (Abstract). Martinsky and Beattie et al. do not teach the method wherein the probe or binding agent is spotted with a pin. However, Balch teaches as similar method for producing a biochip comprising: spotting a binding agent and a plurality of probes onto a biochip wherein said binding agent is capable of immobilizing a probe to the biochip (Column 6, lines 1-24 and Column 18, lines 55-66) wherein the binding agent and probe are spotted with a capillary tube whereby capillary spotting permits small volume spotting with minimal evaporation or cross contamination (Column 12, lines 13-35). It would have been obvious to one of ordinary skill in the art at the time the claimed invention

was made to modify the pin spotting of Martinsky and Beattie et al. with the capillary tube spotting as taught by Balch to thereby minimize evaporation and cross contamination for the expected benefit of efficient and accurate spotting as taught by Balch (Column 12, lines 30-35).

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Conclusion

12. No claim is allowed.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (703) 306-5878. The examiner can normally be reached on 6:45 TO 4:15.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached on (703) 308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-8724 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

BJ Forman, Ph.D.
Patent Examiner
Art Unit: 1655
December 27, 2001

Supervisory Patent Examiner
Technology Center 1600